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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,021	02/09/2005	Yoshiji Yamada	050070	3971

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EXAMINER	
GREENE, JAIME M	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,021	YAMADA ET AL.	
	Examiner	Art Unit	
	Jaime M. Greene	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/9/05.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Upon further review of the restriction requirement mailed 03/15/2007, a further restriction is required. The new restriction requirement is set forth below.

Election/Restrictions

1) Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 and 5, drawn to a method involving genes selected from apolipoprotein E, glycoprotein Ia, Tumor necrosis factor-alpha, G-protein beta3 subunit, apolipoprotein C-III, and angiotensin.

Group 2, claim(s) 2 and 6, drawn to a method involving genes selected from thrombospondin 4, tumor necrosis factor-alpha, thrombomodulin, thrombopoietin, and platelet-activating factory acetylhydrolase.

Group 3, claim(s) 3 and 7, drawn to a method involving genes selected from E-selectin, fatty acid-binding protein 2, glycoprotein Ib-alpha, plasminogen activator inhibitor-1, paraxonase, and apolipoprotein E.

Group 4, claim(s) 4 and 8, drawn to a method involving genes selected from plasminogen activator inhibitor-1, apoliprotein C-III, paraoxonase, glycoprotein Ib-alpha, and apolipoprotein E.

Group 5, claim(s) 9 and 13, drawn to nucleic acids for detecting genes selected from apolipoprotein E, glycoprotein Ia, Tumor necrosis factor-alpha, G-protein beta3 subunit, apolipoprotein C-III, and angiotensin.

Group 6, claim(s) 10 and 14, drawn to nucleic acids for detecting genes selected from thrombospondin 4, tumor necrosis factor-alpha, thrombomodulin, thrombopoietin, and platelet-activating factory acetylhydrolase.

Group 7, claim(s) 11 and 15, drawn to nucleic acids for detecting genes selected from E-selectin, fatty acid-binding protein 2, glycoprotein Ib-alpha, plasminogen activator inhibitor-1, paraxonase, and apolipoprotein E.

Group 8, claim(s) 12 and 16 drawn to nucleic acids for detecting genes selected from plasminogen activator inhibitor-1, apoliprotein C-III, paraoxonase, glycoprotein Ib-alpha, and apolipoprotein E.

2) The inventions listed as Groups 1-8 do not relate to a single general inventive

concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: group 1 requires analyzing a combination of polymorphisms in the genes Apolipoprotein E, glycoprotein Ia, Tumor necrosis factor-alpha, G-protein beta3 subunit, apolipoprotein C-III, and angiotensin, which are not required for groups 2-8. Therefore, there is no unity of invention between groups 1-8.

Additionally, the special technical feature of group V is considered to be a kit for detecting a genotype of two or more nucleic acid groups. Brennen et al. teach a kit comprising an array of every possible ten mer that is capable of detecting a genotype of two or more nucleic acid groups. Brennan et al (US Patent 5474796, Dec. 1995) teaches an array having every possible permutation of a 3mer and a 10mer oligonucleotide (see example 4, column 9, lines 15-60, figure 1.) Claim 9 is drawn to "a nucleic acid for detecting" comprising "apolipoprotein E, glycoprotein Ia, Tumor necrosis factor-alpha, G-protein beta3 subunit, apolipoprotein C-III, and angiotensin" which is broadly interpreted to encompass any fragment of two or more nucleotides of the following apolipoprotein E, glycoprotein Ia, Tumor necrosis factor-alpha, G-protein beta3 subunit, apolipoprotein C-III, and angiotensin genes and can broadly encompasses any magnitude and/or content that comprise at least two nucleotides within apolipoprotein E, glycoprotein Ia, Tumor necrosis factor-alpha, G-protein beta3 subunit, apolipoprotein C-III, and angiotensin which is taught by Brennan. Thus the technical feature linking the recited groups I-VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Further restriction

3) Additionally, each group named above is subject to further restriction.

Applicant is required to further elect a combination of polymorphisms. This is NOT an election of species. Polymorphisms represent structurally distinct chemical compounds and are unrelated to one another. These combinations of polymorphisms are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such combination of polymorphisms is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). Searching more than one of the claimed patentably distinct sequences represents a serious burden to the office.

Applicant is required, for each group above, to elect a single combination of polymorphisms to which the examination will be limited:

Group 1: A single combination of two or more of the polymorphisms listed in claims 1, that will be applied to both claims 1 and 5, to which examination will be limited.

Group 2: A single combination of two or more of the polymorphisms listed in claim 2, that will be applied to both claims 2 and 6, to which examination will be limited.

Group 3: A single combination of two or more of the polymorphisms listed in claim 3, that will be applied to both claims 3 and 7, to which examination will be limited.

Group 4: A single combination of two or more of the polymorphisms listed in claim 4, that will be applied to both claims 4 and 8, to which examination will be limited.

Group 5: A single combination of two or more of the polymorphisms listed in claim 9, that will be applied to both claims 9 and 13, to which examination will be limited.

Group 6: A single combination of two or more of the polymorphisms listed in claim 10, that will be applied to both claims 10 and 14, to which examination will be limited.

Group 7: A single combination of two or more of the polymorphisms listed in claim 11, that will be applied to both claims 11 and 15, to which examination will be limited.

Group 8: A single combination of two or more of the polymorphisms listed in claim 12, that will be applied to both claims 12 and 16 to which examination will be limited.

4) Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5) Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jaime M. Greene whose telephone number is 571-270-3052. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMG 6/11/07

Jamie M. Greene

Sarae Bausch
Patent Examiner AU 1634
6/11/07